

REMARKS**Amendments to the Claims**

Claims 1, 3, 7-8 and 19 have been amended.

Claims 25-31 have been canceled.

Claims 1, 3 and 7-8 have been amended to recite "A method of treating a pathology associated with increased TNF α concentrations relative to normal levels in the joints in a human in need thereof comprising administering to the human..." and to delete reference to "TNF α -mediated disease which results in joint stiffness..." Support can be found in the specification, for example, at page 13, lines 1-8; page 13, line 26; page 57, lines 16-27; page 58, line 1 to page 59, line 14; page 64, lines 3-26; page 100, line 25 to page 101, line 24; page 102, Table 5; page 104, Table 7 and Table 8; and page 105, line 8 to page 106, line 3. In addition, support is found in priority application 07/943,852, filed September 11, 1992, for example, at page 13, lines 5-10; page 13, lines 24-29; page 40, line 25 through page 41, line 6; page 46, lines 6-17; page 47, lines 11-32; page 89, lines 12-27; page 90-91, Table 6 and Table 7; page 91, line 27 to page 92, line 1; and page 92, line 20 to page 93, line 2.

Claim 19 has been amended to recite the method of Claim 18 wherein said single or divided dose is one selected from 0.5, 0.9, 1, 1.1, 1.5, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 or 15 mg/kg per day on at least one of day 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, or 30 or at least one of week 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, or 20. Support is found in the specification, for example, at page 60, lines 15-24. In addition, support is found in the specification of priority application US Serial No. 07/943,852, filed September 11, 1992, for example, at page 42, lines 5-18.

No new matter has been added. Therefore, entry of the amendments into the application is respectfully requested.

Priority

The Examiner states that neither the priority applications nor the instant application provide a sufficient written description of a representative number of species to represent the entire genus of TNF α -mediated disease which results in joint stiffness.

While Applicants respectfully disagree with the Examiner's position and reserve their rights to file continuing or divisional applications to pursue these claims, in order to further prosecution, as discussed above, Claims 25-31 have been canceled and Claims 1, 3 and 7-8 have been amended to recite "A method of treating a pathology associated with increased TNF α concentrations relative to normal levels in the joints," and to delete reference to "TNF α -mediated disease which results in joint stiffness." Dependent Claims 9, 10, 14-16, 18-19 and 21-24 contain the same limitation. Support can be found in the specification, for example, at page 13, lines 1-8; page 13, line 26; page 57, lines 16-27; page 58, line 1 to page 59, line 14; page 64, lines 3-26; page 100, line 25 to page 101, line 24; page 102, Table 5; page 104, Table 7 and Table 8; and page 105, line 8 to page 106, line 3. In addition, support is found in priority application 07/943,852, filed September 11, 1992, for example, at page 13, lines 5-10; page 13, lines 24-29; page 40, line 25 through page 41, line 6; page 46, lines 6-17; page 47, lines 11-32; page 89, lines 12-27; page 90-91, Table 6 and Table 7; page 91, line 27 to page 92, line 1; and page 92, line 20 to page 93, line 2. Therefore, the priority application 07/943,852 (filed September 11, 1992) provides sufficient written description for Applicants' claimed methods of treating conditions related to increased TNF α concentrations relative to normal levels in the joints, and Applicants are entitled to claim the benefit of it. This priority application has been properly referenced on page 1 of the specification in compliance with 35 U.S.C. § 120. Therefore, the priority of all pending claims is at least September 11, 1992.

Rejection of Claims 1, 3, 7-10, 14-16, 18-19 and 21-31 under 35 U.S.C. § 112, first paragraph

The Examiner has rejected Claims 1, 3, 7-10, 14-16, 18-19 and 21-31 under 35 U.S.C. § 112, first paragraph on the grounds that the specification as originally-filed does not contain a written description of "TNF α -mediated disease which results in joint stiffness."

While Applicants respectfully disagree with the Examiner's position and reserve their rights to file continuing or divisional applications to pursue these claims, in order to further prosecution, Claims 25-31 have been canceled. Claims 1, 3, 7 and 8 have been amended to recite "A method of treating a pathology associated with increased TNF α concentrations relative to normal levels in the joints", thereby rendering the rejection moot. Support can be found in the specification, for example, at page 13, lines 1-8; page 13, line 26; page 57, lines 16-27; page 58,

line 1 to page 59, line 14; page 64, lines 3-26; page 100, line 25 to page 101, line 24; page 102, Table 5; page 104, Table 7 and Table 8; and page 105, line 8 to page 106, line 3. Therefore, the application provides sufficient written description for Applicants' claimed methods.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1, 3, 7-10, 14-16, 18-19 and 21-31 under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 1, 3, 7-10, 14-16, 18-19 and 21-31 under 35 U.S.C. § 112, second paragraph as being indefinite in the recitation of "TNF α -mediated disease which results in joint stiffness."

While Applicants disagree with the Examiner's position and reserve their rights to file continuing or divisional applications to pursue these claims, in order to further prosecution, as discussed above, Claims 25-31 have been canceled. Claims 1, 3, 7 and 8 have been amended to delete reference to "TNF α -mediated disease which results in joint stiffness," and Claims 9, 10, 14-16, 18-19 and 21-24 depend from these claims, thereby rendering the rejection moot.

Particularly as amended, the claim terms are clearly defined. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1, 3, 7-10, 14-16, 18-19 and 21-31 under 35 U.S.C. § 102(b)

The Examiner has rejected Claims 1, 3, 7-10, 14-16, 18-19 and 21-31 under 35 U.S.C. § 102(b) as being anticipated by Le et al. (U.S. Patent No. 5,698,195).

While Applicants disagree with the Examiner's position and reserve their rights to file continuing or divisional applications to pursue these claims, in order to further prosecution, as discussed above, Claims 25-31 have been canceled. Claims 1, 3, 7 and 8 have been amended to recite "A method of treating diseases related to increased TNF α concentrations relative to normal levels in the joints." The dependent claims contain the same limitation. Applicants' own priority patent Le et al. (5,698,195) is not prior art under 35 U.S.C. § 102(b) because it was not published more than one year before Applicants' priority date. As indicated above, Applicants are entitled to claim priority to U.S. Application Serial No. 07/943,852 (filed September 11, 1992). Le et al. (5,698,195) was filed over two years later, on October 18, 1994, and published on December 16, 1997.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1, 3, 7-10, 14-16, 18-19 and 21-31 under the Judicially Created Doctrine of Obviousness-type Double Patenting

The Examiner has rejected Claims 1, 3, 7-10, 14-16, 18-19 and 21-31 under the judicially created doctrine of obviousness-type double patenting over Claims 1-13 of U.S. Patent No. 5,919,452 and Claims 1-16 of U.S. Patent No. 5,698,195.

Applicants note this rejection and will file a terminal disclaimer upon indication that the only remaining rejections are the double patenting rejections.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Deirdre E. Sanders
Deirdre E. Sanders
Registration No. 42,122
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133

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